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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/096,593	06/12/1998	STEPHEN D. O'CONNOR	A-64559-3/RT	1989

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EXAMINER

COOK, LISA V

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 10/25/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/096,593

Applicant(s)

O'CONNOR ET AL.

Examiner

Lisa V. Cook

Art Unit

1641

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 20,22,23 and 30-35 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 20, 22, 23, and 30-35 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date: _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                    | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date: _____ | 6) <input type="checkbox"/> Other: _____  |

## DETAILED ACTION

### *Amendment Entry*

1. Applicants response to the Notice of Non-Compliance mailed April 22, 2004 (filed May 26, 2004) and the response to the Office Action mailed April 9, 2003 (filed August 11, 2003) are acknowledged. In the amendment filed therein claims 20, 22, and 23 were modified. While claims 21 and 24-29 were cancelled. New claims 30-35 were added. Currently, claims 20, 22-23, and 30-35 are pending and under consideration.

### *Remarks*

2. Applicant's have indicated that claims 20, and 30-33 have been amended to recite "passivation agent monolayer" to replace "self-assembled monolayers" in response to recent written description requirements and because the definition for the terms are identical. It is noted that no written description rejection is set forth in the prior Office Action mailed April 19, 2003 and a definition citing Applicants intended identical scope of the terms was not found in the disclosure. Applicant is invited to show identical definition of the terms "passivation agent monolayer" to replace "self-assembled monolayers in the disclosure.

*Please note:* Although the claimed apparatus is recited to detect a non-nucleic acid target analyte, this has not been given patentable weight because it is intended use. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art.

If the prior art structure is capable of performing the intended use, then it meets the claim. In a claim drawn to a process of making, the intended use must result in a manipulative

Art Unit: 1641

difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963).

## **NEW GROUNDS OF REJECTION NECESSITATED BY AMENDMENT**

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 20, 22-23, and 30-35 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicant has changed the claim language to read on "passivation monolayer" replacing self assembled monolayer (SAM). However, the interchangeable modification of the two terms is not support by the disclosure. The specification implies that the passivation agent is a spacer not a replacement for the SAM. Applicant is invited to show support for the identical definitions of the two terms "passivation monolayer" and self assembled monolayer (SAM).

### ***Claim Rejections - 35 USC § 102***

Art Unit: 1641

4. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

I. Claims 20, 30, and 34 are rejected under 35 U.S.C. 102(b) as being anticipated by Hollis et al. (WO 93/22678).

Hollis et al. disclose an apparatus (sensor array) meeting the instantly claimed limitation. The apparatus includes a test chamber with an array of first measuring electrodes (test sites), a passivation agent monolayer, a binding ligand covalently attached to the electrode via a spacer, a voltage source and an electronic detector. See abstract, figure 26 A and page 24 lines 5-25 for spacer definition. The test sites are monolithic structures on semiconductor chips or wafers (test chambers). Binding of the test sites is measured by two electrodes at each test site. See page 4 lines 5-9 and line 16. The test site may be employed to identify target molecules such as polynucleotides, DNA, RNA, cells, antibodies, or anti-antibodies. See page 8 lines 20-22. Two electrodes at each test site measure the binding of the target to the test site. See page 4 lines 5-9 and line 16.

The test site also includes upper and lower electrodes covered with a film and measures voltages in relationship to target molecule binding, hybridization, or interaction. See page 11 lines 14-32. The sensor array contains binding ligands (such as short oligonucleotide strands) attached to the test site. See page 13 lines 11-21.

Art Unit: 1641

The arrays are not limited to only oligonucleotide reagents but can be other ligands to make different probes. The probes can be attached directly to the electrodes or solid support substrates (spacer) via covalent linkage. See page 24 lines 5-25. In one embodiment the sensor array probes include a passivating layer (passivation agent monolayer). See figure 26 and page 29 line 27-30. The sensors can be evaluated with a microfluidic detector. See page 34-35, for example.

***Claim Rejections - 35 USC § 103***

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Art Unit: 1641

II. Claims 22-23 and 31-33 are rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al. (WO 93/22678) in view of Kayyem et al. (U.S. Patent #6,221,583) and in further view of Kossovsky et al. (U.S. Patent #5,585,646).

Please see Hollis et al. (WO 93/22678) as set forth above.

Hollis et al. (WO 93/22678) differ from the instant invention in failing to specifically teaching passivation agent monolayers or self-assembled monolayer devices/apparatus including insulators and/or conductive oligomers.

However, Kayyem et al. teach devices which include both insulators and conductive oligomers. Kayyem et al. further disclose that oligomers can exist in the apparatus as an insulator. See column 6 lines 24-57 and column 22 line 66 through column 24 line 42.

While, Kossovsky et al. disclose improved bioelectronics devices in comprising a layer of a polyhydroxy oligomer that is spaced between the surface of a semi conductive material (applicant's monolayer) and an electronically active biochemical molecule (applicant's binding ligand) which is bound to the semi conductive surface of an electronic device (applicant's electrode). The layer of polyhydroxy oligomer functions as a biochemical stabilization layer to prevent denaturation of the electronically active biochemical molecule (Abstract).

The stabilization layer is made up of one or more polyhydroxy oligomers. Exemplary polyhydroxy oligomers include carbohydrates, carbohydrate derivatives, and other macromolecules with carbohydrate like components. Kossovsky et al. further teach that the surface modification concept and the electron donor-acceptor concept can be combined at the semiconductor surface and utilized in various methods.

Art Unit: 1641

Hollis et al. (WO 93/22678) in view of Kayyem et al. (U.S. Patent #6,221,583) and in further view of Kossovsky et al. (U.S. Patent #5,585,646) are analogous art because they are from the same field of endeavor, all three inventions teach the fabrication/utility of electrochemical biosensors.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to incorporate the insulators and/or conductive oligomers taught by Kayyem et al. and Kossovsky et al. in the apparatus/device of Hollis et al. to perform analyte detection in an affinity assay system because Kayyem et al. taught that insulators serve to inhibit or slow electron transfer (column 24 lines 25-27) and conductive oligomers increase the rate of electron transfer and are more conductive than the insulators (column 6 lines 25-47). Further, Kossovsky et al. disclosed that the use of self assembled monolayers [reading on passivation agents or a type of SAM] allows the molecules to be held in a specific orientation with respect to the metal and are applicable in many system designs (Column 4, Lines 12-25).

recent advances have extended self-assembled monolayers beyond the prototype gold/thiol systems. Fatty acids on aluminum, silanes on silicon, isonitriles on platinum and rigid phosphates on metals are all examples.

Kossovsky et al. also teach the use of the any denaturization of the biochemical material which might be caused by the semiconductor material is eliminated or substantially reduced by placing the stabilization layer of polyhydroxy oligomers between the biochemical material and the semiconductor (Column 7, Lines 13-18).



Art Unit: 1641

One of ordinary skill would have been motivated to employ insulators and or conductors (oligomer) to control electron transfer in binding systems like the one of Hollis et al. to ensure optimal working ranges for precise and accurate evaluation of an analyte of interest.

III. Claim 35 is rejected under 35 U.S.C. 103(a) as being unpatentable over Hollis et al. (WO 93/22678) in view of Wohlstadter et al. (U.S. Patent #6,090,545).

Please see Hollis et al. (WO 93/22678) as set forth above.

Hollis et al. (WO 93/22678) differ from the instant invention in failing to specifically teach a processor for data analysis in their device designs.

However, Wohlstadter et al. disclose patterned, multi-array multi-specific surfaces on a support (PMAMS) that are electronically excited in electrochemiluminescence (ECL) based tests. The PMAMS can be generated from self- assembled monolayers on a surface. (column 13, lines 10-31). In figure 47 shows an embodiment in which the multi-array apparatus/device includes a microprocessor/computer containing controller means for generating and analyzing ECL signals. See column 7 lines 38-40. The apparatus further provides a voltage source and photon detector. Column 3 lines 59-65 and column 22 Voltage Waveform.

Hollis et al. (WO 93/22678) and Wohlstadter et al. (U.S. Patent #6,090,545) are analogous art because they are from the same field of endeavor, both inventions teach the fabrication/utility of electrochemical biosensors.

Art Unit: 1641

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use a processor/computer to analyze the generated device signals as taught by Wohlstadter et al. in the apparatus/device of Hollis et al. (WO 93/22678) to perform analyte detection because Wohlstadter et al. indicate that "computer controlled voltage systems" are advantageous. Specifically the computer/processor can be used to select a particular electrical potential or a particular range of electrical potentials over a predetermined time. Column 24 line 63 to column 25 line 5.

One of ordinary skill would have been motivated to do this in order to control the device reaction parameters and produce accurate/reproducibly data analyses in rapid time.

### *Response to Arguments*

5. Applicant's arguments filed 8/11/03 have been fully considered and were found persuasive. Specifically, Applicant contends that the electrode of Ribí (5,571,568) does not include passivation agents and the incorporation of the spacer/insulating agent of the instant invention would render the device of Ribí inoperable. Accordingly, the patent to Ribí (5,571,568) has been withdrawn. However new rejections, including the reference to Hollis et al. (WO 93/22678) are set forth above to make the instant invention (passivation agent monolayer) obvious.

6. For reasons aforementioned, no claims are allowed.

Art Unit: 1641

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

8. Papers related to this application may be submitted to Group 1600 by facsimile transmission. Papers should be faxed to Group 1600 via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Group 1641 – Central Fax number is (703) 872-9306, which is able to receive transmissions 24 hours/day, 7 days/week. In the event Applicant would like to fax an unofficial communication, the Examiner should be contacted for the appropriate Right Fax number.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lisa V. Cook whose telephone number is (571) 272-0816. The examiner can normally be reached on Monday - Friday from 7:00 AM - 4:00 PM.

Art Unit: 1641

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le, can be reached on (571) 272-0823.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

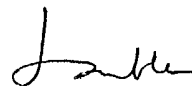


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*7/23/04*



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**SUPERVISORY PATENT EXAMINER**  
**TECHNOLOGY CENTER 1600**

*10/18/04*